UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI,

15 Civ. 9414

Plaintiff,

OPINION

-against-

NEUROCRINE BIOSCIENCES, INC.,

Defendant.

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A P P E A R A N C E S:

Attorneys for Plaintiff

CROWELL & MORING LLP
590 Madison Avenue
New York, NY 10022
By: Chieme Suzuki, Esq.
Honor Costello, Esq.

CROWELL & MORING LLP
275 Battery Street, 23rd Floor
San Francisco, CA 94111
By: Gregory Call, Esq.
Mark T. Jansen, Esq.
Pilar R. Stillwater, Esq.

Attorneys for Defendant

LATHAM & WATKINS LLP (NY)
885 Third Avenue
New York, NY 10022
By: Benjamin Naftalis, Esq.
Daniel G. Brown, Esq.

LATHAM & WATKINS
12670 High Bluff Drive
San Diego, CA 92130
By: Jake Ryan, Esq.
Stephanie N. Grace, Esq.

LATHAM & WATKINS (DC)
555 Eleventh Street, NW, Suite 1000
Washington, DC 20004
By: Michael A. Morin, Esq.

Sweet, D.J.

The Defendant Neurocrine Biosciences, Inc. ("Neurocrine" or the "Defendant") has moved pursuant to F. R. Civ. P. 12(b)(6) to dismiss the complaint of the plaintiff Icahn School of Medicine at Mount Sinai ("Mt. Sinai" or the "Plaintiff"). Upon the conclusions set forth below, the motion is granted in part and denied in part.

These two well-advised sophisticated parties are participants in a complicated and demanding process of the research and development required to discover, identify, and develop drugs to effect a biological response to treat a disabling disease. Both Defendant and Plaintiff contend that the motion can be determined by a simple reference to the carefully drafted agreement which established the parties' relationship and industry practice. However, Neurocrine submits the reference compels a grant of the motion, while Mt. Sinai contends it will result in denial. The resolution is not as simple as the parties contend, as what follows will hopefully demonstrate.

The complicated process of discovering and developing new drug treatments requires basic research such as is performed by Mt. Sinai and its scientists. The application of that science

to particular conditions such as endometriosis and uterine fibroids was performed by Neurocrine. The testing, approval, and manufacture of the new drug is performed by a major pharmaceutical company, in this instance Abbott International Luxembourg S.a.r.l. ("Abbott"), now AbbVie Inc. ("AbbVie"). The agreements under which this process can be accomplished have generated substantial and significant litigation, of which this preliminary motion is an example.[1]

Prior Proceedings

Mt. Sinai filed its complaint on December 1, 2015 alleging a breach of contract by Neurocrine's unauthorized sublicensing of certain rights to AbbVie, which Neurocrine had received under a license from Mt. Sinai and also by Neurocrine's failure to provide Mt. Sinai annual development reports and a

[1] See, e.g., *Cook Inc. v. Boston Scientific Corp.*, 333 F.3d 737, 743 (7th Cir. 2003) (reading through the five related contracts to find that "the only purpose of the transaction being to transfer Cook's patent rights to ACS in circumvention of the anti-assignment clause."); *Gene Codes Forensics, Inc. v. City of New York*, No. 10 Civ. 1641 (NRB), 2012 WL 1506166, at *5 (S.D.N.Y. April 26, 2012) (the City could use the licensed technology in perpetuity, but only the licensed technology created during the contract term and not "created after the expiration of the License Agreement"); *MedImmune, LLC v. PDL BioPharma*, Inc., No. C 08-5590, 2011 WL 61191, at *17-20 (finding that under the parties' agreement Abbot was not a sublicensee or de facto licensee); *Prima Tek II, L.L.C. et al. v. A-Roo Co.*, 222 F.3d 1373, (Fed. Cir. 2000) (finding that "[a] licensee's right to sub-license is an important consideration in evaluating whether a license agreement transfers all substantial rights").

copy of the agreement governing product development with AbbVie, as allegedly required by the License Agreement.

The instant motion to dismiss the complaint was heard and marked fully submitted on March 17, 2016.

The Complaint

The complaint describes the parties, their history, and the Plaintiff's contentions.

Plaintiff, formerly known as Mt. Sinai School of Medicine of the City University of New York, is a New York education corporation, organized under the New York Education Law and chartered by the Board of Regents of the State of New York. Its sole member is Mt. Sinai Health System, Inc., a not-for-profit corporation organized under the laws of the State of New York. Mt. Sinai has a principal place of business at 1 Gustave L. Levy Place, New York, NY 10029-6574. Mt. Sinai owns and controls certain rights in technology for the identification, discovery, and screening of drug compounds that interact in the human body with receptors for the hormone known as GnRH. Mt. Sinai's drug-discovery tools are foundational in

the identification, screening, and development of drugs for the treatment of a number of endocrine disorders, and Mt. Sinai has the exclusive right to grant licenses to the patented technology directed thereto. (Compl., ¶ 20.)

Neurocrine is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 12780 El Camino Real, San Diego, CA 92130. Neurocrine is in the business of, among other things, developing pharmaceuticals for use in neurological and endocrine diseases and disorders. (Compl., ¶ 22.)

AbbVie Inc. ("AbbVie") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is in the business of, among other things, pharmaceutical development, manufacturing and sales.

Gonadotropin releasing hormone ("GnRH") is implicated in numerous endocrine diseases including prostate cancer, ovarian cancer, breast cancer, and endometriosis. (Compl. ¶¶ 3, 38, 40-43.) Stuart C. Sealfon, M.D., a world-renown neurologist

at Mt. Sinai, was the first to make stable cell lines expressing the cloned receptor for GnRH ("GnRH-R") and invented a method to identify drug compounds that modulate the receptor's molecular signaling using the cell lines. (*Id.* ¶¶ 39-40.) Dr. Sealfon's patented inventions, assigned to Mt. Sinai, are foundational drug-discovery tools. Both Parties recognized the Sealfon tools as essential for Neurocrine to identify and develop new drugs that inhibit GnRH activity and can be used to treat endocrine disorders. (*Id.* ¶¶ 5, 40-46, 50.)

The parties, on August 27, 1999, entered into a Nonexclusive License Agreement ("License Agreement") which provided that Neurocrine may "grant sublicenses under the License only with the prior written consent" of Mt. Sinai. (Compl. Ex. 1, D.I. 1-1 ("License Agreement") § 2.1(c).) During their negotiations, the Parties recognized that if Neurocrine identified a promising drug candidate, Neurocrine likely would sublicense the remainder of the drug development efforts, which require expensive Phase 3 clinical trials, to a major pharmaceutical corporation. (Compl. ¶¶ 47, 54, 57.) Neurocrine sought an unconditional right to sublicense the licensed rights to third parties. (*Id.* ¶¶ 54-55.) As reflected in Section 2.1(c), the Parties agreed to a future negotiation for the right

to grant sublicenses. (Compl. ¶¶ 56-57.) The Parties intended that Mt. Sinai would, consistent with industry practice, receive additional consideration, such as a share of revenues paid by a future sublicensee. (*Id.*)

Given the foundational nature of the Sealfon drug discovery tools, the Parties recognized that both the identification of beneficial drug compounds, and their subsequent development through commercialization, would depend on the use of the licensed tools. (*Id.* at ¶ 50.) The expected drug candidates could not be discovered, and subsequently developed, "but for" the use of the Mount Sinai licensed technology. (*Id.*) To reflect this understanding, the Parties defined these enabled drugs, i.e., all drugs "identified or discovered using" the Sealfon tools, as "Licensed Products." (*Id.*; License Agreement § 1.5.)

The License granted to Neurocrine by Mt. Sinai is alleged to also broadly extend to the development of the enabled drugs. (Compl. ¶ 48-49; License Agreement §§ 1.6, 2.1(a).) Neurocrine received a "worldwide license to make and use the subject matter covered under the Licensed Patent Rights to identify, screen for, and/or develop products." (License

Agreement § 1.6.) Neurocrine has explained over the years in its filings with the SEC that the License Agreement is a "license to certain patents and patent applications related to GnRH, to develop and commercialize licensed products worldwide," or that, "[i]f we were to default on our obligations . . . we could lose some or all of our rights to develop, market and sell products covered by the licenses." (Compl. ¶¶ 49, 70.)

Neurocrine used the licensed Sealfon tools to identify "Elagolix" as a strong candidate for treating endocrine disorders. (Compl. ¶ 58.) Neurocrine had contractual obligation to provide annual development reports, including a "complete written list of Licensed Products discovered in the previous year" (License Agreement § 3.5; which it breached; Compl. ¶¶ 67-76), Neurocrine discovered Elagolix not later than early 2001 (Compl. ¶ 60).

Neurocrine reported successful Phase 2 results for Elagolix in 2006, 2009, and finally on May 24, 2010. (*Id.* ¶¶ 60-64, 67-69.)

In January 2008, with Elagolix showing great promise, Neurocrine began discussions with Abbott International, now

AbbVie, for AbbVie to license rights to develop and commercialize Elagolix and other GnRH-antagonist drugs discovered by Neurocrine using the Sealfon tools. Neurocrine contacted Mt. Sinai shortly after the discussions with AbbVie began and informed Mt. Sinai that it was in discussions to sublicense the Sealfon tools to an unnamed company. (Compl. ¶ 66.) Neurocrine recognized it needed to obtain Mt. Sinai's consent for the intended sublicensing. (*Id.*) Neurocrine never sought Mt. Sinai's consent to sublicense to AbbVie. (*Id.* at ¶ 67.) Market analysts have predicted AbbVie will sell $1.2 billion worth of Elagolix each year after its expected approval by the FDA for treatment of endometriosis and uterine fibroids. (*Id.* ¶¶ 86-87.)

On June 15, 2010, Neurocrine and AbbVie publicly announced their agreement (the "AbbVie Agreement") under which "Abbott will receive worldwide exclusive rights [from Neurocrine] to develop and commercialize Elagolix and all next-generation GnRH antagonists, for women's and men's health." (*Id.* ¶ 77 and Compl. Ex. 2, D.I. 1-2 ("Press Release") at 1.) Neurocrine did not seek or obtain Mt. Sinai's consent before transferring the drug development program to AbbVie. (*Id.* ¶¶ 54-57, 71).

Neurocrine initially refused to provide Mt. Sinai a complete, unredacted copy of its June 2010 agreement with AbbVie, but subsequently provided it. (*Id.* ¶¶ 77-78, 91.) The AbbVie Agreement excluded rights under Mt. Sinai's license from the definition of "Neurocrine Technology" (AbbVie Agreement § 1.50), notwithstanding that it referenced the Mt. Sinai License and licensed technology. "Non-peptide GnRH Antagonists," defined as organic chemical compounds of a certain size that bind to the "GnRH Receptor" (*id.* §§ 1.37, 1.51), are the subject of the AbbVie Agreement (see *id.* at Recitals). "GnRH Receptor" in turn is defined as the receptor "claimed in United States patent 5, 750, 366," - the Sealfon patent owned by Mt. Sinai. (*Id.* § 1.37, Compare Compl. ¶ 41.)

Neurocrine, through the AbbVie Agreement, transferred to AbbVie an "exclusive worldwide license . . . to research, develop, make, have made, use, sell, offer for sale, import and/or otherwise exploit" (*id.* § 3.1), defined as "Follow-on Compound[s]" (see *id.* §§ 3.1, 1.32) all of which are "Licensed Products" under the Mt. Sinai-Neurocrine License Agreement. (Compl. ¶¶ 74, 93-94, 96.) The AbbVie Agreement also requires Neurocrine to transfer to AbbVie as part of a "Transition

Program," "all data, information, Technology and assets related to the Compounds and Products" that are the subject of the agreement. (Compl. ¶¶ 74, 94 (citing AbbVie Agreement § 6.1(d)).) The "Technology" includes "all proprietary data, information, and materials" (*id.* § 1.69) related to Compounds and Products.

AbbVie also received the right and power to take over, and direct and control, the contemplated GnRH drug research and development. (Compl. ¶¶ 14, 16, 74, 92, 95-97, 100 (citing AbbVie Agreement §§ 5.1-5.6, 6.1-6.2, 7.1-7.3).) The AbbVie Agreement gives AbbVie final say in all work done by the parties' "Joint Development Committee" ("JDC"), and AbbVie controls funding for all activities related to transitioning the drug development program and continuing drug research and development under a "Collaborative Development Program." (AbbVie Agreement §§ 5.1, 5.3(a), (c), 5.6, 6.1, 6.2, 7.2(a), 7.3(a)-(b).)

The AbbVie Agreement provided insistence that Neurocrine provide a warranty that it will maintain in force and will not, "without Abbott's prior written consent, terminate or

otherwise modify the terms of . . . the Receptor License." (*Id.* § 2.2(h).)

Neurocrine's failure to seek and obtain Mt. Sinai's written consent to the transaction with AbbVie allegedly deprived Mt. Sinai of its bargained-for right to approve, in exchange for to-be-negotiated consideration, Neurocrine's alleged sublicense of the product research and development rights licensed by Mt. Sinai. (E.g., Compl. ¶¶ 4, 17, 74, 80, 98.)

Applicable Standard

On a motion to dismiss pursuant to Rule 12(b)(6), all factual allegations in the complaint are accepted as true, and all inferences are drawn in favor of the pleader. *Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1174 (2d Cir. 1993). A complaint must contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 1964, 167 L. Ed. 2d 929 (2007)). A claim is facially plausible when "the plaintiff pleads factual content that allows the court

to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 663 (quoting *Twombly*, 550 U.S. at 556). In other words, the factual allegations must "possess enough heft to show that the pleader is entitled to relief." *Twombly*, 550 U.S. at 557 (internal quotation marks omitted).

Additionally, while "a plaintiff may plead facts alleged upon information and belief 'where the belief is based on factual information that makes the inference of culpability plausible,' such allegations must be 'accompanied by a statement of the facts upon which the belief is founded.'" *Munoz-Nagel v. Guess, Inc.*, No. 12-1312, 2013 WL 1809772, *3 (S.D.N.Y. Apr. 30, 2013) (quoting *Arista Records, LLC v. Doe 3*, 604 F.3d 110, 120 (2d Cir. 2010)); *Prince v. Madison Square Garden*, 427 F. Supp. 2d 372, 384 (S.D.N.Y. 2006); *Williams v. Calderoni*, No. 11-3020, 2012 WL 691832, *7 (S.D.N.Y. Mar. 1, 2012)). The pleadings, however, "must contain something more than . . . a statement of facts that merely creates a suspicion [of] a legally cognizable right of action." *Twombly*, 550 U.S. at 555 (citation and internal quotation omitted).

Discussion

Mt. Sinai alleges that Neurocrine has breached the parties' Licensing Agreement for the patents described above by: (1) sublicensing the patents to AbbVie; and (2) violating ongoing disclosure and reporting requirements. Neurocrine brings this motion to dismiss the complaint because it argues it did not sublicense Mt. Sinai's patents to AbbVie, it was not obligated to provide Mt. Sinai with a copy of the AbbVie Agreement, and that Mt. Sinai did not suffer any damages even if Neurocrine did not provide certain reports and lists of licensed products. For the reasons that follow, the motion to dismiss is denied with respect to the sublicensing argument (except for the argument that Mt. Sinai has no rights to Neurocrine Licensed Products, which is granted) and the motion to dismiss is also denied with respect to Neurocrine's obligations to produce the AbbVie Agreement and the damages argument.

Mt. Sinai Adequately Alleged that Neurocrine Breached the Licensing Agreement

Mt. Sinai adequately alleged that Neurocrine breached certain aspects of the Licensing Agreement. Breach of contract consists of: (1) the existence of a contract; (2) the plaintiff's performance; (3) the defendant's breach; and (4)

resulting damages. E.g., *Morris v. 702 E. Fifth St. HDFC*, 46 A.D.3d 478, 479 (1st Dep't 2007). "[W]here questions exist as to whether a party has performed or breached the agreement . . . , dismissal prior to fact discovery is inappropriate." *Campbell v. Mark Hotel Sponsor, LLC*, No. 09 Civ. 9644 WHP, 2010 WL 3466020, at *4 (S.D.N.Y. Sept. 3, 2010) (denying motion to dismiss breach of contract claims and citing *Boston Concessions Grp., Inc. v. Criterion Ctr. Corp.*, 606 N.Y.S.2d 696 (1st Dep't 1994)).

Neurocrine does not dispute the adequacy of Mt. Sinai's allegations that support elements (1), (2), or (4) and that Defendant failed to obtain Mt. Sinai's consent. Instead, Neurocrine argues that it has not breached the agreement because its agreement with AbbVie is not a sublicense (and that there were no damages for the other theories other than the sublicense issue).

The Complaint alleges three distinct and independent sets of facts constituting the unconsented sublicense with AbbVie. First: Neurocrine promised to transfer to AbbVie all "Technology" and assets "related" to the transferred GnRH antagonist products and the to-be identified "Follow-on Compounds," alleged to be "Licensed Products" under the Mt.

Sinai License Agreement. (AbbVie Agreement §§ 1.69, 6.1(d); Compl. ¶¶ 16, 74, 92, 94.) Second: Neurocrine transferred to AbbVie all rights to research, develop, manufacture and sell drugs that are "Licensed Products" under the License Agreement. (AbbVie Agreement § 3.1; Compl. ¶¶ 16, 74, 92-93.) Third: Neurocrine transferred to AbbVie the right and power to control and direct the use of the licensed Sealfon discovery tools in research and development into Elagolix and "Follow-on Compounds" through control of the JDC. (AbbVie Agreement §§ 5.1-5.6, 6.1-6.2, 7.1-7.3; Compl. ¶¶ 16, 74, 92, 95-97.)

Mt. Sinai has adequately pled violations of the License Agreement under the first and third arguments, but not with respect to the second argument that Neurocrine transferred to AbbVie all rights to research, develop, manufacture and sell drugs that are "Licensed Products" under the License Agreement.

The Complaint Adequately Alleged a Violation of the License Agreement

Neurocrine contends that its AbbVie Agreement is not a sublicense because the definition of the "Neurocrine Technology" in Section 1.50 of the AbbVie Agreement explicitly does not

include Neurocrine's rights under the Mount Sinai Receptor License.

However, "where . . . the rights of third parties [such as Mt. Sinai here] are involved, the relationship between contracting parties must be determined by its real character rather than by the form and color that the parties have given it." *In re Shulman Transp. Enters., Inc.*, 744 F.2d at 295 (citing *Quackenbos v. Sayer*, 62 N.Y. 344, 346 (1875) and collecting cases); see also, e.g., *Cook Inc. v. Boston Sci. Corp.*, 333 F.3d 742, 743 (7th Cir. 2003) (citing *Shulman*, purported sale, processing, and resale contracts amounted to a prohibited sublicense or assignment); *E.I. du Pont de Nemours & Co., Inc. v. Shell Oil Co.*, 498 A.2d 1108, 1113-14 (Del. 1985); *Lee v. Marvel Enters., Inc.*, 386 F. Supp. 2d 235, 246 (S.D.N.Y. 2005).

Mt. Sinai has relied on *DuPont*, where the Delaware Supreme Court concluded that the arrangement between two companies was a prohibited sublicense because "it is the overall effect of such Agreements, rather than their precise label, which will determine whether such an arrangement amounts to a sublicense." 498 A.2d at 1115. On the other hand, Neurocrine

argues that *DuPont* does not apply here because the facts in *DuPont* involved a "sham" transaction in which a third party, Carbide, made and sold the patented articles on its own, while claiming it did not have a sublicense because of a carefully worded agreement. *Id.* at 1115-16.

On balance, the holding of *DuPont* applies beyond its precise facts. *DuPont* was concerned that, "We cannot countenance such legerdemain whereby Shell sought to free itself from the contract language by which it agreed to be bound under the License Agreement with DuPont." *Id.* at 1116. It is that same concern that is at issue in this case. Neurocrine manipulated the contractual language in Section 1.50 of its agreement with Abbvie by excluding Neurocrine's rights under the Mt. Sinai Receptor License from the definition of Neurocrine Technology in the Abbvie Agreement. This formulation appears to be an attempt by Neurocrine to avoid any potential obligations under the Licensing Agreement with Mt. Sinai.

The specific allegations underlying Mt. Sinai's claim that Neurocrine's agreement with AbbVie constitutes a sublicense demonstrate why the first argument survives the motion to dismiss. The Complaint (¶¶ 16, 74, 92, 94, 96, 100) alleges that

Neurocrine's agreement to transfer the Sealfon tools to AbbVie resulted in an unauthorized sublicense of the Mt. Sinai technology. Neurocrine, in Section 6.1(d) of the AbbVie Agreement, agreed to transfer to AbbVie any and all "Technology" (a defined term) "related to" the transferred GnRH antagonist drugs, i.e., Elagolix, and the "Follow-on Compounds." The term, "Technology," is defined in Section 1.69 of the AbbVie Agreement, to include:

> all proprietary data, information, and materials (including Inventions, know-how, trade secrets, experimental data . . . experimental procedures, . . . molecules, assays, reagents, compounds, compositions, human or animal tissues, samples or specimens).

(AbbVie Agreement § 1.69.) Thus, it is alleged that Neurocrine without obtaining Mt. Sinai's prior written consent (License Agreement § 2.1(c)), gave AbbVie full rights to take and use the licensed Sealfon discovery tools and related cell lines "related to" Elagolix and the Follow-on Compounds. (See Compl. ¶¶ 16, 74, 94; compare AbbVie Agreement §§ 1.19, 1.32, 1.59, 1.60, with License Agreement §§ 1.5, 2.1(c).)

Further, Mt. Sinai alleged that this agreement to transfer the licensed Sealfon tools for AbbVie's use results in a sublicense. This is because a sublicense is a "contract granting to a third party a portion or all of the rights granted to the licensee under an original license," SUBLICENSE, Black's Law Dictionary (10th ed. 2014), or a transfer or sharing of the licensee's rights with another (see, e.g., *Biosynexus, Inc. v. Glaxo Grp. Ltd.*, 11 Misc. 3d 1062(A), at *6-7 (Sup. Ct. N.Y. Cnty. 2006)). As one court explained in *Nano-Proprietary, Inc. v. Canon Inc.*, No. A 05 CA 258 SS, 2007 WL 628792, at *6 (W.D. Tex. Feb. 22, 2007) (applying New York law), aff'd in part, rev'd in part, 537 F.3d 394 (5th Cir. 2008). Here, in order to prevail on a breach of contract claim Mt. Sinai "does not have to show [AbbVie] actually used its patented material, only that [Neurocrine] purported to give [AbbVie] license to do so." *Id.* Mt. Sinai has pled facts sufficient to allege that Neurocrine licensed at least a portion of the rights from its agreement with Mt. Sinai in its agreement with AbbVie.

Mt. Sinai further contends that Neurocrine and AbbVie opted to draft Section 6.1(d) of the AbbVie Agreement to require a transfer of the broader category "Technology," rather than "Neurocrine Technology," because they specifically intended the

transfer to cover a broader class of materials, namely, the Sealfon tools and cell lines. See, e.g., *Novella v. Westchester Cnty.*, 661 F.3d 128, 142 (2d Cir. 2011) (applying "the textual canon of expression unius est exclusio alterius" to find the omission of a term from contract provision in favor of another term was deliberate).

Mt. Sinai dismisses the provision excluding Neurocrine's rights under the License Agreement as "artful wording" just as the "legerdemain" that the court rebuffed in *DuPont*. (Pltf. Memo in Opp., p. 9; *DuPont*, 498 A.2d at 1116.) Mt. Sinai has contended that the reasoning in *DuPont* applies and in effect that the exclusionary language is contradicted by other provisions in the AbbVie Agreement. By the conduct of the parties, Mt. Sinai has adequately alleged that the validity of the exclusionary language survives the motion to dismiss.

The AbbVie Agreement Does Not Violate the Licensed Products Provision

Mt. Sinai has alleged in its second contention about the breach for the sublicense that Neurocrine transferred all rights to research, develop, manufacture and sell drugs that are Licensed Products to AbbVie as part of a sublicense in breach of

the License Agreement. However, the "License" Mt. Sinai granted to Neurocrine included the right to develop and commercialize any products discovered using those patents, as long as Neurocrine paid Mt. Sinai a royalty of 1% of net sales of Licensed Products, which includes any product identified or discovered using Mt. Sinai's patented receptor or any product that could not have been discovered or developed without infringing Mt. Sinai's patents, such as Elagolix.

Mt. Sinai has contended that the License extends to the development of Elagolix and all other drug products discovered—or enabled—using the Sealfon tools as "Licensed Products." (License Agreement § 1.5.) The Parties defined "Licensed Products" as follows:

> "Licensed Products" means any product that modulates the activity of the GnRH-R and is (a) identified or discovered using the GnRH-R [claimed by Mt. Sinai's Licensed Patent Rights], or (b) could not have been discovered or developed without infringing the Licensed Patent Rights.

(Compl. ¶¶ 6, 50 (citing License Agreement §1.5); see also License Agreement §§ 1.2 and 1.4 (defining "Licensed Patent Rights" and "GnRH-R").)

The License also stated:

> "License" means the nonexclusive worldwide license to make and use the subject matter covered under the Licensed Patent Rights to identify, screen for, and/or develop products.

(License Agreement § 1.6; Compl. ¶ 48.)

According to Mt. Sinai, these definitions of Licensed Products and License are so broad as to demonstrate that the license intended to include downstream development of the drugs discovered using the licensed Sealfon tools, even if Mt. Sinai's tool is used only in the "drug discovery" phase of research. (See Compl. ¶¶ 5, 50-51.)

However, this contention cannot be supported by a plain reading of the definitions of these terms. The Mt. Sinai and Neurocrine License Agreement defines the "License" as the "nonexclusive worldwide license to make and use the subject matter covered under the Licensed Patent Rights," which were defined as the "valid and issued or pending claims included in . . . the U.S. patent and patent applications listed on the attached Exhibit A." Ex. 2 at § 1.2. Those patents relate only to drug-discovery tools rather than the yet-to-be-discovered

compounds. No provision in the License Agreement has been cited to give Mt. Sinai rights to future IP created out of the performance of the Agreement, other than the description of Licensed Products. See, e.g., *Aspex Eyewear, Inc. v. Altair Eyewear, Inc.*, 361 F. Supp.2d 210, 215 (S.D.N.Y. 2005).

Neurocrine owns all the patents to Elagolix, see Ex. 5 at Ex. C, and Mt. Sinai has not challenged ownership of those patents. Mt. Sinai also claims that "a license can extend to drugs that [a]re discovered using licensed drug discovery tools" even where the patentee holds rights only over the drug-discovery tool, and not over the resulting product, Opp'n. at 16 n.5, and cites only to *Bayer AG v. Housey Pharm.*, 228 F. Supp.2d 467, 470 (D. Del. 2002). There, the court held that, in some cases, a patentee can tether royalties for the drug-discovery tool to sale of the yet-to-be-discovered compounds; it did not say that the license itself would "extend" to those compounds or that a party could grant "rights" to a compound over which it had no protectable IP interest. Here, although the parties tethered royalties to the sale of the compounds Mount Sinai has not adequately alleged that any rights to those compounds were covered in the License grant.

"Licensed Products" was the nomenclature the parties used to describe the compounds Neurocrine identified using the drug-discovery tools. See Ex. 2. Further, Neurocrine has contended its only obligations with respect to the "Licensed Products" were to provide development reports, indemnify Mt. Sinai for product liability claims, and pay a royalty to Mt. Sinai based on sales. Ex. 2 at §§ 3.3, 3.5, 6. For these reasons, Neurocrine's motion to dismiss is granted with respect to this argument that there was no sublicense for these described Licensed Products.

Mt. Sinai Has Adequately Alleged Violation of the License Agreement by a de Facto Sublicense

Mt. Sinai has alleged a third contract breach theory, that Neurocrine effected a de facto sublicense by granting AbbVie the ultimate right to direct and control the use of the licensed Sealfon tool through the JDC. (Compl. ¶¶ 16, 74, 95-97.) Like the first theory, this third theory also survives the motion to dismiss because it sufficiently alleges a triable issue of fact. A licensee's agreement to use licensed patent rights at the direction and under the control of a third party can result in an unauthorized *de facto* sublicense in violation of the prohibition against sublicensing. See, e.g., *Cook*, 333

F.3d at 742-43) (comparing original license and unauthorized third party license as the "traditional task of a finder of fact").

The Complaint alleges adequately that Neurocrine transferred to AbbVie the right to direct and control the continued use of the licensed Sealfon tools to research and develop both Elagolix and follow-on GnRH antagonist drugs. (Compl. ¶¶ 14, 16, 74, 95-97 (citing AbbVie Agreement §§ 5.1-5.6, 6.1-6.2, 7.1-7.3).) While the AbbVie Agreement describes a JDC to govern research and development of the GnRH program, the agreement cedes to AbbVie the ultimate decision-making authority and financial control over the JDC and the research and development to be performed. (License Agreement §§ 5.3(b),(c), 6.2, 7.3(a).)

The JDC established by the AbbVie Agreement governs all "Collaboration" between Neurocrine and AbbVie, including a "Transition Program" and a "Collaborative Development Program." (*Id.* §§ 5.1, 5.3(b) ("The JDC will be responsible for coordination and oversight of all activities conducted under the Transition Program and the Collaborative Development Program . . . .").) The AbbVie Agreement provides AbbVie final say in

all matters governed by the JDC: "If for any reason the JDC cannot resolve any matter properly before it . . . the senior business executive of Abbott shall have final decision-making authority." (*Id.* § 5.3(c).) The agreement also provides that AbbVie "shall have sole responsibility and authority with regard to (a) Development activities related to Products . . . , (b) manufacturing and commercial supply of Products . . . , and (c) Commercialization of Products, including pricing . . . and all other terms of sale." (Id. § 5.6.)

AbbVie is alleged to hold final decision-making authority over the JDC, and control over any product development activities, including the research exclusively transferred to it by, e.g., Sections 3.1 and 6.1(d). Mt. Sinai has adequately alleged this breach theory is a de facto sublicense (discussed further below) because Mt. Sinai has alleged that AbbVie holds substantial control over the research through the JDC. Discovery will help to show whether in practice, this proves to be true.

AbbVie is also given financial control of all research and development conducted under the Transition Program and Collaborative Development Program. (Id. §§ 6.2, 7.3, 7.4(a).) (id. § 6.2). Section 6.2 provides that the Transition Budget for

the Transition Program—the goal of which is to transfer all of Neurocrine's ongoing work and materials to AbbVie (id. 6.1(b), (d))—will be funded by AbbVie and shall not exceed a set amount "without Abbott's prior written permission" (id. § 6.2).

The Neurocrine-AbbVie "Collaborative Development Program," is also controlled and funded by AbbVie. (*Id.* §§ 7.3(a) ("Abbott will provide funding for Neurocrine [activities] devoted to the conduct of the Collaborative Development Program . . . ."); 7.3(b) ("Abbott will be responsible for all Third Party and external costs and expenses approved in advance by Abbott for the Collaborative Development Program activities.").) As with the Transition Program, the Collaborative Development Program also cannot exceed a set amount without AbbVie's prior written approval. (Id. § 7.3(a)-(b).)

The stated purpose of the Collaborative Development Program is "to achieve further development of one or more Compounds," (Id. § 7.1(a)), including "follow-on Compounds" (id. by Neurocrine (as Defendant tries to argue (Mot. At 3)), but also new compounds to be identified through research directed and controlled by AbbVie subsequent to June 2010 (see Compl.

¶¶ 94-96; AbbVie Agreement §§ 1.18). Identification of these, or any other as-yet untested new GnRH antagonist compounds are alleged to require use of the Selfon tool. (See Compl. ¶¶ 40, 45, 95-96; see also AbbVie Agreement §§ 1.37 (defining GnRH receptor as that claimed in the Sealfon patent); 2.2(h) (requiring Neurocrine to maintain the Mt. Sinai License in full effect).)

AbbVie's control over the Collaborative Development Program also cautions the Court to allow Mt. Sinai's claims to survive the motion to dismiss. For the same concerns articulated about the JDC and as will be further discussed below, if these allegations are true, then the arrangement with AbbVie could constitute a de facto sublicense.

Neurocrine has contended that the transfer of that power to AbbVie does not effect a de facto sublicense. Under *Cook* and others giving AbbVie the power to direct the exercise of licensed rights (see Compl. ¶¶ 74, 95-97), Neurocrine may have granted an unauthorized sublicense depending upon the factual situation. See *Cook*, 333 F.3d at 741-743; *Du Pont*, 498 A.2d at 1115-16 (test for a sublicense is "whether the production is by or for the use of the original licensee or for

the sublicensee himself or for someone else"). Whether Neurocrine or AbbVie employs the Mt. Sinai tools remains a factual issue that survives this motion to dismiss.

Accordingly, the Complaint adequately pleads a breach of the License Agreement based on Neurocrine's grant of an unauthorized de facto sublicense that arose when Neurocrine transferred to AbbVie the right to exclusively direct and control use of the Sealfon drug discovery tools.

Mt. Sinai has Adequately Pled Reporting Related Theories of Breach, Including that It Suffered Damages

Neurocrine does not dispute it breached Section 3.5 of the License Agreement by failing to provide required "Development Reports," but contends that Mt. Sinai has not adequately alleged damages caused by these technical breaches. The Court disagrees. The Complaint alleges that Mt. Sinai was harmed by Neurocrine's breaches because Mt. Sinai was unable to oversee and ensure protection of its property interests, such as the ability to control the terms of future royalty payments on sales of Licensed Products by any licensees or sublicensees under the License Agreement; to ensure the right to audit sales by sublicensees; and to ensure that Mt. Sinai was given an

opportunity to negotiate the terms of any future sublicenses as contemplated by the Parties in the License Agreement. (See Compl. ¶¶ 53 (citing License Agreement § 3.5), 77, 79-80, 91.) These allegations are sufficient and the motion to dismiss this allegation is denied.

Conclusion

Upon the conclusions set forth above, the motion of Neurocrine to dismiss the Mt. Sinai complaint is denied.

It is so ordered.

New York, NY
June 13, 2016

ROBERT W. SWEET
U.S.D.J.